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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/800,918 | 03/16/2004 | Claude Singer | 1662/495071 | 9628 |
| 23838 | 7590 | 07/19/2004 | EXAMINER | |
| KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005 | | | HABIB, KAH SAY | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 1624 |

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SAR

Office Action Summary

| | | |
|------------------------------|----------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/800,918 | SINGER ET AL. |
| | Examiner Kahsay Habte, Ph. D. | Art Unit 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 29-51 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 29-48 and 50 is/are rejected.
- 7) Claim(s) 49 and 51 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. Claims 29-51 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-39 are rejected under 35 U.S.C. 102(b) as being unpatentable over Kaspersen *et al.* Kaspersen *et al.* on page 1066 teaches crystallization of mirtazapine crude product from methanol/water to achieve colorless crystals. In claims 29-39, there has been recited a crystalline adduct or an adduct of mirtazapine and the method of its preparation (precipitation from organic solvents such as alcohols). It appears to be the same process and therefore the products are presumed to be the same, i.e. inherently formed. See *In re Zelinski* 141 USPQ 217, *In re Best* 195 USPQ 432, and *In re Wiegand* 86 USPQ 155.

3. Claims 40-47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kaspersen *et al.* {Journal of Label. comp. and Radiopharm., 27, No. 9, 1055 (1989)}. Kaspersen *et al.* teaches the multi-step synthesis of Org-3770 (mirtazapine) on page 1058 (Fig.4). On page 1066, Kaspersen *et al.* teaches the synthesis of mirtazapine and the crystallization of the mirtazapine (compound 1c) from the crude product using

methanol/water solvent mixture to achieve almost pure crystals. Compound **1c** is ¹³carbon labeled product, but since the claim embraces the labeled compounds, the crystals product acquired from this process are identical to the claimed crystals of mirtazapine. The synthesis of compound **1d** on page 1067 also can be used as an additional prior art, even though Kaspersen et al. did not provide any information on the specific nature of the product (solid, crystal, or oily). Since compound **1c** and **1d** are the same compounds, therefore compound **1d** is also presumed to be crystal. These products (crystals from compound **1c**) including compound **1d**, are exactly the same compounds (crystals of mirtazapine) claimed by the applicants.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: In claims 48 and 51, the phrases, "about 90% or greater" or "about 95% greater" are not clear. The term "greater" is ambiguous when it follows "about 90%" or "about 95%". For example for the phrase "about 90% or greater", it is unclear if the term "greater" applies to the 90% (i.e. greater than 90%, e.g. 91%) or if it applies for the phrase "about 90%" (i.e. greater than about 90%, e.g. 88%, 89%, 90%, 91%, etc.). The latter covers both greater and lower percentage numbers of the 90%. The same is true for the phrase "about 95% or greater". If the greater applies

Art Unit: 1624

to the "95%", percentage numbers such as 96%, 97% are covered. In other hand, if the term "greater" applies to "about 95%", percentage numbers such as 94%, 95.2%, 96%, etc. are covered. Suggested is "about 90% or greater than 90%" for claim 48 and "about 95% or greater than 95%" for claim 50. Note that claim language in claims 49 and 51 are acceptable.

Objection

5. Claims 49 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

KH
July 14, 2004


Mark L. Berch
Primary Examiner
Art Unit 1624